K033611

APR 2 7 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Mary L. Verstynen
Director of Clinical Affairs

Proprietary Name: Calcigen™-NaP Bone Void Filler

Common Name: Calcium Sodium Phosphate Bone Void Filler

Classification Name: Resorbable calcium salt bone void filler device
(21 CFR 888.3045)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- EBI OsteoStim™ Granules – Resorbable Bone Graft Substitute (EBI L.P.; K011386)
- α-BSM® Bone Substitute Material (DePuy Orthopaedics, Inc; K011048)
- Pro Osteon® 500R Resorbable Bone Graft Substitute (Interpore Cross; K990131, K980817)
- Norian® SRS® Bone Void Filler (Synthes USA; K011897)
- 3i® Calcium Sodium Phosphate Bone Cement (Biomet, Inc; K003493)

Device Description:
Calcigen™-NaP Bone Void Filler is a synthetic, self-setting paste for use as a bone graft substitute. The product is provided in pre-measured quantities of powder and setting solution. The two components are mixed together intra-operatively to form a thick, moldable paste that is then applied to the bone void or defect. The paste can be shaped to completely fill the bone defect and hardens in-situ to prevent migration out the defect area. It is designed to be applied/delivered to the defect either using a spatula or equivalent instrument or injected thru a syringe into open defects. The material is resorbed and replaced by bone during the healing process.

Intended Use:
Calcigen™-NaP Bone Void Filler is intended for filling bony voids of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. The device is intended for bone voids or gaps that are not intrinsic to the structural integrity of the bony structure.

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Summary of Technologies:
Calcigen™-NaP Bone Void Filler is shown by analysis of available information to be identical in intended use and equivalent in materials and form to currently marketed similar products. The product is identical in chemistry and formulation to 3i® Calcium Sodium Phosphate Bone Cement.

Non-Clinical Testing:
The information presented demonstrates that the Calcigen™-NaP Bone Void Filler is substantially equivalent to currently marketed predicate devices. The differences between Calcigen™-NaP Bone Void Filler and the predicates are not significant and have already been shown not to present additional safety or efficacy issues.

Clinical Testing:
None is provided as the basis of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 7 2004

Ms. Mary L. Verstynen
Director of Clinical and Regulatory Affairs
Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K033611
Trade/Device Name: Calcigen™-NaP Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: January 28, 2004
Received: January 30, 2004

Dear Ms. Verstynen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033611

Device Name: Calcigen™-NaP Bone Void Filler

Indications For Use:

Calcigen™-NaP Bone Void Filler is intended for filling bony voids of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. The device is intended for bone voids or gaps that are not intrinsic to the structural integrity of the bony structure.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033611